UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

SW

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/714,093	11/16/2000	Frank Butaric	CRD-834	5116

7590 12/28/2004

PHILIP S. JOHNSON
ONE JOHNSON AND JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
MILLER, CHERYL L	
ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/714,093	BUTARIC ET AL.	
	Examiner	Art Unit	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 19, 2004 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1 and 3-5 have been considered but are moot in view of the new ground(s) of rejection. Applicant has amended the independent claim to include the limitation "wherein the union of each of the plurality of sinusoidal rings and each of the plurality of hoops is made at the apex of at least one diamond configuration of the plurality of hoops and the apex of at least one intersection of the plurality of alternating struts of the sinusoidal rings", which applicant has argued the previously applied references do not disclose. The examiner disagrees. See explanation below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 3-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Fogarty et al. (USPN 6,193,745, cited in previous office action). Fogarty discloses a radially expandable stent having proximal and distal open ends and a longitudinal axis between (fig.6C), the stent deployable in a body vessel, the stent comprising a plurality of hoops comprising a plurality of interconnected struts forming a substantially diamond shaped pattern (end hoops are diamond, see fig.6c; see attachment), the stent having a proximal and a distal hoop, the end hoops configured to have greater radial and longitudinal strength than the hoops between (strength in both directions may be varied anywhere along the stent, col.3, lines 20-26; col.4, lines 5-10; col.19, lines 49-51; col.20, lines 3-5), wherein the proximal hoop is flared (fig.6C), a plurality of sinusoidal rings (all rings between two end hoops may be sinusoidal, wherein 2 rings adjacent form a diamond, or two rings criss crossing over one another form a diamond) connecting adjacent hoops (end hoops), the rings being formed from a plurality of alternating struts, the plurality of alternating struts being substantially shorter in length than the plurality of interconnected struts of the plurality of hoops (Fogarty discloses varying the length of the individual stent hoops at different locations along the stent, col.3, lines 15-27), wherein the union of each plurality of sinusoidal ring and each of the plurality of hoops is made at the apex of at least one diamond configuration of the plurality of hoops and the apex of at least one intersection of the plurality of alternating struts of the sinusoidal rings (union seen in fig.14, where struts 222 meet is an apex and tab 224 being the union, or struts 222 may be interpreted to extend to the end of 224, the end of 224 being an apex and the union being the overlapping of two 224's; also, depending on how loose or tight the tabs are tied together, the apexes of 222 are capable of overlapping), proximal and distal attachment devices (220, fig.14) for securing a graft member

(172) to the stent (222), the proximal attachment device positioned distal of the proximal open end (located between adjacent hoops or rings, therefore, not at an end, fig.14), such that the proximal open end of the stent is exposed to the body vessel (fig.3B and 6C show portions of the end hoops exposed to the vessel, although it is noted to the applicant that a graft has not been positively claimed, therefore location of a graft is irrelevant) the proximal and distal attachment devices comprising tabs (224) formed from the joining of two struts and having at least two apertures (228).

Referring to claims 3-4, Fogarty discloses a self-expanding stent, made of superelastic nickel titanium (col.19, lines 54-55).

Referring to claim 5, Fogarty discloses an end hoop having a larger diameter than an adjacent hoop (fig.3, 3A, 4, 6C).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim (USPN 6,270,524 B1, cited in previous office action) in view of Lombardi et al. (USPN 6,579,314 B1, cited in previous office action). Referring to claims 1 and 5, Kim discloses a radially expandable stent (see figure 2A) having proximal and distal open ends and a longitudinal axis therebetween comprising a plurality of hoops (end hoops in fig.2A) comprising a plurality of interconnected struts (20) forming a substantially diamond shape configuration (end hoops in

fig.2A are diamond shaped), the stent having a proximal end hoop and a distal end hoop, wherein the distal end hoop and the proximal end hoop are configured to have greater radial and longitudinal strength than the hoops therebetween (will inherently be stronger in both directions due to their shape being more interconnected than the rings 14 therebetween), a plurality of sinusoidal rings (14) connecting adjacent hoops (end diamond hoops) to one another, the sinusoidal rings being formed from a plurality of alternating struts (20), the plurality of alternating struts (20) being substantially shorter in length than the plurality of interconnected struts (20) of the plurality of hoops (see attachment 1), wherein the union of each of the plurality of sinusoidal rings and each of the plurality of hoops is made at the apex of at least one diamond configuration of the plurality of hoops and the apex f at least one intersection of the plurality of alternating struts of the sinusoidal rings (22 unions an apex of two 21's with other apex of two 21's; 22 being the union) and proximal and distal attachment devices (connector 22, see embodiment 104 in fig.10; although Kim does not disclose attachment to the graft by connectors, applicant has not positively claimed a graft connected to the stent, and the attachment devices of Kim are ***capable*** of securing a graft member to the stent, thus still read on the claim), the proximal attachment device (22, 104) being positioned distal of the proximal open end of the stent (fig.2A) such that the proximal end hoop of the stent is configured to be exposed to a body vessel (will be inherently exposed, if the graft is not present, because applicant has not positively claimed a graft), the proximal and distal attachment devices (104) comprising tabs (110) formed from the joining of two struts (103) and having at least two apertures therein (fig.10). Kim discloses the invention substantially as claimed, however does not disclose flared end hoops. Lombardi teaches in the same field of radially expandable stents, a stent (12) having a plurality

of hoops and plurality of sinusoidal connecting rings, the stent having flared ends (14; fig.1) for the purpose of better anchorage of the stent in the vessel (col.4, lines 54-57; col.6, line 46-49). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Kim's radially expandable stent with Lombardi's teaching of flaring ends of stents, in order to provide a stent which will better anchor in the vessel.

Referring to claims 3-4, Kim discloses a self-expanding stent, made of superelastic nickel titanium (col.7, lines 64-67; col.8, lines 34-50).

Claims 1 and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berry et al. (USPN 6,231,598 B1, cited in previous office action) in view of Freidberg et al. (USPN 6,699,277 B1, cited in previous office action). Berry discloses a radially expandable stent (see figures 15, 16, 17, 18, and 20; col.8, lines 36-39) having proximal and distal open ends and a longitudinal axis between, the stent deployable in a body vessel, the stent comprising a plurality of hoops (14) comprising a plurality of interconnected struts (15, 16, 13) forming a substantially diamond shaped pattern (figs.15, 16, 17, 18, 20), the stent having a proximal (63) and a distal hoop (63'), the end hoops configured to have greater radial and longitudinal strength than the hoops between (col.17, lines 22-25), and the proximal hoop being flared (col.21 line 62-col.22 line 8), a plurality of sinusoidal rings (75, 108, 21) connecting adjacent hoops (col.9, lines 1-3; col.10, lines 26-32), the rings (75, 108, 21) being formed from a plurality of alternating struts, the plurality of alternating struts being substantially shorter in length than the plurality of interconnected struts of the plurality of hoops (14), see figures 15-20, wherein the union of each of the plurality of sinusoidal rings and each of the plurality of hoops is made at the apex of at

least one diamond configuration of the plurality of hoops and the apex f at least one intersection of the plurality of alternating struts of the sinusoidal rings (unions 36, 68; see figures 15, 17, 18). Berry does not disclose however, proximal and distal attachment devices. Freidberg teaches in the same field of radially expandable stents, proximal and distal attachment devices (51, see figures 11-14) placed on any conventional stent (col.3, lines 7-14) comprising tabs (52, 57, 59) formed from the joining of two struts (struts on both sides of tab 52, 57, and 59) and having at least two apertures (eyelets, 53, 58, 60) spaced from the end of the stent, in order to attach a stent (55) to a graft (22), so that restenosis is reduced in the vessel (col.2, lines 1-5, 59-67; col.8, lines 35-57). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the stent structure of Berry with Freidberg's teaching of attachment devices and their location, on a stent, in order to attach a graft to a stent, thereby reducing any chance of restenosis in the vessel.

Referring to claims 3-4, Berry discloses a self-expanding stent, made of superelastic nickel titanium (col.8, lines 60-63; col.18, lines 45-62).

Referring to claim 5, Berry discloses an end hoop having a larger diameter than an adjacent hoop (col.22, lines 1-7).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cheryl Miller

BRUCE SNOW
PRIMARY EXAMINER